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Editorial Comment

Role of Peer Review of Pacemaker Implantations*

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The present study. In this issue of the Journal, Falk (1) has raised but not entirely answered a number of important and provocative questions concerning the cost and quality of medical care. He has shown that there was no evidence, at least in Massachusetts, that the review system discouraged the use of pacemakers or that needless implantations were performed. Only 5 (0.27%) of 1,860 requests were denied, and only 3.7% fewer pacemakers were implanted in 1984 than during each of the preceding 3 years. (In New Jersey for the year ending December 1989, only 3 [0.09%] of 3,242 pacemaker applications were denied [D. D. Griffith, personal communication].) The issue of cost savings resulting from the review process deserves further scrutiny.

The peer review organizations (PROs), independently managed by each state, are funded by the federal Health Care Financing Administration (HCFA) at a cost of $325 million per year. Full preoperative review is required in all instances for 10 frequently performed and expensive operations; review of 2 of these types of operations is mandated by the PRO and 8 are chosen by the state from a master list. Pacemaker implantation is one of those optional procedures selected by many states for full review. The full-time reviewers, often nurses but sometimes clerks with less clinical expertise, approve or disallow the procedure on the basis of a checklist of information that must be provided by the applicant. In some areas, the PRO also decides whether a single or dual chamber pacemaker is appropriate. Contested cases are reviewed by a physician. About 10% of the precertified cases also are subjected to retrospective review. The penalty for noncompliance is denial of reimbursement to the physician and the hospital.

Massachusetts may not be representative of other states. It is conservative in temperament (remember the "banned in Boston" days) and has a heavy academic influence. An influential and widely attended Boston pacing group meets twice yearly and promulgates good pacing practices. Boston is also the home of the North American Society of Pacing and Electrophysiology (NASPE), a professional society devoted solely to education and quality of care. Falk (1) points out, however, that even in those states where there are higher implantation rates and more frequent denials of requests for implantation, there is little evidence of cost-effectiveness. The HCFA itself has reported that, nationwide, for the 2 years ending December 1987 only 265 (0.44%) of 59,798 requests were denied.

Does the review process save money? Assume that denials were issued in 130 cases during 1 year (about one half of the 265 reported denials) and that pacemakers were therefore not implanted (although patients might subsequently have returned for implantation). Assume further that each implantation, including hospitalization and 1 year of follow-up, costs Medicare $24,000 (H. Krakauer, personal communication). Then, the review process for pacemakers would save Medicare $3.12 million per year. The cost to Medicare for pacemaker implantations (antitachyarrhythmic devices excluded) was $1.4 billion in 1988 (H. Krakauer, personal communication). Elimination of 130 pacemakers would thus reduce the overall cost of pacing by 0.22%.

But at what price is this savings achieved? In 1989 preoperative certification and retrospective review by the PRO in New Jersey cost $9 per procedure (D. D. Griffith, personal communication). The cost of reviewing 29,899 pacemaker applications per year (one half of the 59,798 for 2 years reported by the HCFA) would therefore be about $269,100, reducing the total Medicare savings to $2,851,000 (0.2% of the annual cost of pacing). Thus, the review process appears to provide relatively little financial benefit.

These estimates, however, have not included the cost to physicians and hospitals of filing the applications, which is probably of the same order of magnitude as the costs of review. Those of us who live and work within the system are acutely aware of other costs, such as the labor and the nuisance of collecting data from outpatient records, referring physicians, Holter monitor reports and electrophysiologic studies, not to mention the numerous and sometimes frustrating telephone calls to uninformed or indifferent chart reviewers.

It seems justifiable to ask, therefore, whether we are getting our money's worth in spending $0.5 million per year (excluding indirect costs) on reviewing pacemaker applications to deny only 0.4% of the implantations, especially if there is no provable impact on the quality of care. It takes only a very small leap of logic to wonder whether the same is not true for the entire PRO program. Its abandonment

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would save us $375 million per year. Surely there are better ways to spend that money.

Maintaining standards and guidelines for pacemaker implantation. But is cost saving all that the PROs were created to achieve? Certainly there was an interest in quality of care and in avoidance of needless surgery. If unnecessary pacing were rampant, however, would not the denial rate be closer to 20% than to 0.44%? Are things perhaps actually as good as they seem? The importance of establishing and maintaining good standards of practice cannot be overemphasized. Shortly after the 1981 "revelations" of overusage to which Falk refers (2), several authoritative guidelines on indications for pacing were published (3,4). The "revelations" may have been far from correct, as revealed by Scherlis and Dembo (5) and others in subsequent reviews, but the guidelines had a tangible impact in that those criteria were then widely applied in one form or another to PRO regulations. Moreover, NASPE has become a larger and more influential society. Although the organization remains a relatively unappreciated and pesky orphan among senior cardiology societies, it provides high quality policy statements on numerous pacing issues, it fosters the publication of *PACE*, a bimonthly journal on pacing and electrophysiology, and it encourages the establishment of good standards in pacing through an examination of special competence in pacing, the NASPExAM (6), prepared for clinicians and associated professionals in cooperation with the National Board of Medical Examiners. Thus the quantity, quality and dissemination of pacemaker education have greatly improved.

Financial constraints have come into play quite on their own. The prospective payment system based on Diagnosis-Related Groups (DRGs) has made hospital finances tight. Administrators have begun to keep a watchful eye on pacemaker implantation rates, and multihospital, bulk purchase programs have been instituted that restrain unbridled use of the more elaborate (and expensive) devices. Without further study it is hard to identify all the factors that limit the implantation rate. Perhaps the mere existence of PROs has had an influence. It is not only Falk (1), however, who has questioned the effectiveness of the review process. One PRO executive stated off the record that, in his view, precertification is not cost-effective, and others have said that the entire process was designed primarily to "get the doctor."

Conclusions. In a recent editorial, Jaffe (7) expressed the belief that the PRO type of quality assurance system assumes that the physician is guilty until proved innocent and puts him at risk of litigation. Jaffe considers the system flawed, "expensive, divisive, misdirected, and discriminatory." The recent review by Imperiale et al. (8) of the Connecticut PRO, in which a limited number of denials was documented, sparked several angry letters questioning the entire process (9–13) and largely echoing the sentiments of our group. It must be acknowledged that some aspects of pacing make it an easy target for outside criticism. Peer review is difficult because pacing is not clearly identified as either a surgical or a medical subspecialty. Guidelines for training and education recommended by the American College of Cardiology and the American Heart Association have not been officially adopted by institutions or subspecialty boards. Finally, collaboration between manufacturers and physicians in the evaluation of new devices and, particularly, excessive reliance on sales representatives in the hospital create an atmosphere of mistrust.

The community would be better served if these issues were corrected. Instead of being subjected to costly control by amateurs, pacing should be recognized as a subspecialty, practiced by duly accredited physicians and then supervised through tried and true methods of peer review, such as mortality and morbidity conferences. This approach would provide superior quality control as well as tangible savings to society.

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